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Section 7 - 510(k) Summary of Safety and Effectiveness

7.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

7.2 Submitter	Endius, Inc. 23 West Bacon Street Plainville, MA 02762

7.3 Company Contact	Gene DiPoto VP of Engineering 508-643-0983 ext. 104

7.4 Device Name	**Proprietary Name:** Endius Cervical Plate System **Common Name:** Anterior Cervical Plating System **Classification Name:** Spinal Intervertebral Body Fixation Orthosis.(KWQ)

7.5 Predicate Legally Marketed Devices	The Endius Cervical Plate System is substantially equivalent to the Window Dynamic Plate System Plate System manufactured by Endius, Inc. (Plainville, MA.)

7.6 Device Description	The Endius Cervical Plate System is a set of implants designed to be implanted via an anterior approach to the cervical spine. The system includes various plates and screws manufactured from Titanium. The material used in the manufacture of the components in the Endius Cervical System meets ASTM F136 for Ti 6A1-4VELI.
7.7 Device Indications and Intended use	The Endius Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and /or failed previous fusions. Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine
7.8 Substantial Equivalence	The Endius Cervical Plate System is substantially equivalent to the Window Cervical Spinal System. Following is a table that describes the features of the new and the predicate systems that indicate substantial equivalence. Testing was also completed as per ASTM F1717 in order to demonstrate equivalence.

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7.9 Table of Substantial Equivalence

Device Name	The Endius Cervical Plate System	Window Cervical System
Product Components	Plates of various lengths, 4mm screws, 4.3mm revision screws	Identical components with identical specifications
Indications for Use	See above	Identical
Materials	Titanium	Titanium
Product Labeling	Instructions for use and box labeling including all of the necessary warning statements	Instructions for use and box labeling including all of the necessary warning statements
Packaging/ Sterilization	Non-sterile, single use only	Non-sterile, single use only
Biomechanical Testing	Meets ASTM F1717	Meets ASTM F1717

Applicant Gene DiPoto Date 12/12/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2002

Mr. Gene DiPoto
Vice President of Engineering
Endius Incorporated
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K014107
Trade Name: Endius Cervical Plate System
Regulation Number: 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 12, 2001
Received: December 13, 2001

Dear Mr. DiPoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K014107

Device Name: Endius Cervical Plate System

Indications for Use:

The Endius Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and /or failed previous fusions.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014107